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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/089,009 | 08/06/2002 | Carolyn K. Goldman | NIH-05111 | 5287 |

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LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

| EXAMINER | |
|---|---|
| JIANG, DONG | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/089,009 | GOLDMAN ET AL. | |
| | Examiner | Art Unit | |
| | DONG JIANG | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,5,9,11-15,23 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,9,11-15,23 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED OFFICE ACTION**

Applicant's amendment filed on 21 December 2007 is acknowledged and entered. Following the amendment, claim 9 is amended.

Currently, claims 1, 3, 5, 9, 11-15, 23 and 26-29 are pending and under consideration.

***Rejections under 35 U.S.C. 112:***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the previous Office Actions mailed on 6/16/06, 11/1/06 and 8/23/07.

Applicants argument filed on 21 December 2007 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 6-7 of the response, the applicant argues that the Office assumes that if anti-Tac binds IL-2R and ILRAP associates with IL-2R, then an IP with anti-Tae *must* co-IP all ILRAPs, which is unrealistic as all binding interactions involving an antigen are somehow transitive and that, consequently, any time an antibody-antigen complex is pulled down, the pulled down complex should also include every protein associated with the antigen to a similar extent; that the Office has provided no basis for contradicting Applicants actual data showing that using anti-Tac to pull down IL-2R, does not pull down enough (if any) of the claimed ILRAP so as to be identifiable by SDS-PAGE (the March 2006 Waldmann Declaration, Exhibit 3); that the absence of ILRAP in lane 2 of Exhibit 3 is readily explainable: the amount of IL-2R interacting with ILRAP (under IP conditions) is so much smaller than the total amount of IL-2R pulled down

with anti-Tac, that immunoprecipitation of IL-2R with anti-Tac did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE of Exhibit 3. This argument is not persuasive for the following reasons: on page 9 of the response, applicants argue, with respect to the prior art rejection, that the first Waldmann Declaration submitted on 6/17/05 provides evidence that pre-clearing cell extracts with anti-Tac antibody does not remove the claimed ILRAPs and that the claimed ILRAPs are present in cells that do not include the antigen for anti-Tac and 7GT/B6, indicating that the claimed ILRAPs differ from that of the prior art by Colamonici, as Colamonici's polypeptides can be pre-cleared with anti-Tac antibody. Such a statement contradicts the earlier argument indicating that anti-Tac did co-IP the claimed ILRAPs, and it just did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE. It seems that applicants are arguing both ways for different reasons: on one hand, applicants argue that anti-Tac did co-IP the claimed ILRAPs, and it just did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE, indicating the association of the claimed ILRAPs with IL-2R, therefore, the claims are enabled. On the other hand, applicants argue strongly that anti-Tac antibody does not remove the claimed ILRAPs, suggesting that anti-Tac antibody did not co-IP the claimed ILRAPs, therefore, they are distinct from that of the prior art. It is unclear what applicants intend to argue, but applicants cannot argue both ways as they are mutually exclusive. Further, with respect to applicants argument that the claimed ILRAPs are present in cells that do not include the antigen for anti-Tac and 7GT/B6, if this is the case, applicants have not provided evidence that the claimed ILRAPs are IL-2R associated polypeptides because IL-2R (i.e., "the antigen for anti-Tac and 7GT/B6") are not present in the cells.

Further, claim 9 and its dependent claims remain further rejected because enablement would not be commensurate in scope with the claims, for the reasons of record set forth in the last Office Action mailed on 8/23/07.

Applicants argument filed on 21 December 2007 has been fully considered, but is not deemed persuasive for the reasons below.

At page 8 of the response, the applicant argues that claim 9 has been amended to recite an ILRAP with molecular weight of about 32,000 to 34,000 Da or about 26,000 to 28,000 Da as determined by SDS-PAGE, which are plainly disclosed throughout the Specification. This

argument is not persuasive because the main issue is not about the precise MW, rather, the main issue is lack of the identity of the polypeptide being purified because the claim recites neither a specific source of polypeptide (a specific cell, for example), nor a specific antibody, which would ensure targeting the disclosed polypeptides. The claim, as written, encompasses polypeptides only with the similar MW, but distinct molecules from that in the instant application. The skilled artisan would not know how to make a commensurate number of species, and it would require undue experimentation make encompassed IL-2R associated polypeptides prior to use the claimed invention in its full scope.

***Rejections Over Prior Art:***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J.

Immunol., 1990, 145:155-160), for the reasons of record set forth in the previous Office Actions mailed on 6/304, 4/19/05, 10/18/05, 6/16/06, 11/1/06 and 8/23/07.

Applicants argument filed on 15 June 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 9-12 and 13 of the response, the applicant presents similar arguments in response to the previous Office Actions, with a focus on criticizing the prior art reference and without further supporting evidence that the claimed ILRAPs are distinct from that of the prior art by Colamonici. These arguments are not persuasive for the reasons of record as they have been addressed in detail in the previous Office Actions. Applicants argue, on page 9 of the response, that the first Waldmann Declaration submitted on 6/17/05 provides evidence that pre-clearing cell extracts with anti-Tac antibody does not remove the claimed ILRAPs and that the claimed ILRAPs are present in cells that do not include the antigen for anti-Tac and 7GT/B6, indicating that the claimed ILRAPs differ from that of the prior art by Colamonici, as Colamonici's polypeptides can be pre-cleared with anti-Tac antibody. However, as addressed above, on page 7 of the response, applicants argue, with respect to the enablement rejection, that anti-Tac did co-IP the claimed ILRAPs, and it just did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE. Such clearly does not support applicants argument regarding the distinctness between the claimed ILRAPs and that of the prior art by Colamonici.

At page 12-13 of the response, the applicant argues, in response to the last Office Action, that applicants have shown that the claimed polypeptide differs from the prior art in terms of MW, that the difference was established in the same cells as taught by the prior art and the difference was observed in the same gel, that the only remaining reason offered by the Office for why the difference "could be" an artifact, relates to differences in amount of polypeptide loaded in lanes 2 and 3 of Exhibit 1 in the March 2006 Waldmann Declaration, which is based purely on speculation. This argument is not persuasive because the reason offered by the Office is based on applicants data, which do not show a clear distinctness between the claimed ILRAPs and that of Colamonici. Further, the only evidence that the present invention depends on is the "difference" in MW, as the specification discloses neither the structural identity nor a functional property of the polypeptides (with respect to IL-2R, at least it is unclear whether the claimed

ILRAPs are associated with IL-2R, for the reasons above). As the only "difference" is indecisive and could be explained by experimental deviation, the examiner is unable to determine whether it distinguishes the claimed ILRAPs over that of the prior art, and the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Given the fact that the prior art discloses molecules from the same cells and with similar MW on SDS-PAGE and IL-2R association, and lack of sufficient evidence from applicants demonstrating distinctness between the claimed ILRAPs and that of Colamonici, applicants argument is unsound.

***Conclusion:***

No claim is allowed.

***Advisory Information:***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/12/08

/Olga N. Chernyshev, Ph.D./

Primary Examiner, Art Unit 1649